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Proposed Re-evaluation Decision PRVD2016-03

Fludioxonil

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Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the fungicide fludioxonil, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of products containing fludioxonil for sale and use in Canada.

An evaluation of available scientific information found that products containing fludioxonil do not pose unacceptable risks to human health or the environment when used according to the proposed label directions. As a requirement of the continued registration of fludioxonil, new risk reduction measures are proposed for the end-use products registered in Canada. Additional label statements based on current labelling requirements are also proposed.

This proposal affects all pest control products containing fludioxonil registered in Canada. Once the final re-evaluation decision is made, registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for fludioxonil and presents the reasons for the proposed re-evaluation decision. It also proposes new risk reduction measures to further protect human health and the environment.

This consultation document is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of fludioxonil.

The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2012-02, *Re-evaluation Program Cyclical Re-evaluation*, presents the details of the cyclical re-evaluation approach.

For more details on the information presented in this overview, please refer to the Science Evaluation of this consultation document.

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[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

What Is Fludioxonil?

Fludioxonil is a broad-spectrum fungicide that belongs to the phenylpyrrole group of fungicides. In Canada, it is used as a seed treatment to control soil-and seed-borne fungal pathogens on a large number of crops, including potato seed pieces, as a foliar spray on food and feed crops, greenhouse vegetables, outdoor ornamentals and turf, and as a postharvest dip or drench on stone fruits, pome fruits, sweet potato, potato and carrot. It is applied by ground and aerial application equipment by growers, farm workers, nursery workers and professional applicators.

Health Considerations

Can Approved Uses of Fludioxonil Affect Human Health?

Fludioxonil is unlikely to affect human health when used according to the proposed label directions.

Potential exposure to fludioxonil may occur through the diet (food and water), when mixing, loading and applying the product, by entering treated sites, or by handling treated crops/commodities. When assessing health risks, two key factors are considered: the levels at which no health effects occur in animal testing and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only those uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

Dietary exposure, occupational mixer/loader/applicator exposure, postapplication exposure and non-occupational exposure are not of concern under the current conditions of use.

There was insufficient data available to conduct risk assessments for pelleting small seeds using a liquid formulation and for commercial treatment of potato seed pieces using a dust formulation. Therefore, labels will be updated to clarify that these uses are not permitted.

Environmental Considerations

What Happens When Fludioxonil Is Introduced Into the Environment?

Fludioxonil is not expected to pose an unacceptable risk to the environment when used according to the proposed label directions.

Fludioxonil can enter nontarget terrestrial and aquatic habitats through spray drift and can enter aquatic habitats through runoff and leaching. In terrestrial environments, fludioxonil is persistent in soil and is expected to carry over to the following growing season. Fludioxonil is not soluble in water, binds tightly to soil and is not expected to reach ground water. In aquatic environments, fludioxonil is persistent and is expected to move to sediment. Fludioxonil is not likely to accumulate in plant and animal tissue.

Fludioxonil may pose a risk to birds, mammals and aquatic organisms for certain uses at the labelled application rates. To minimize the potential risks of fludioxonil, additional risk reduction measures are proposed.

When fludioxonil is used in accordance with the label and the proposed risk-reduction measures are applied, the resulting environmental risk is considered to be acceptable.

Value Considerations

What Is the Value of Fludioxonil?

Fludioxonil controls a broad range of important fungal diseases and contributes to fungicide resistance management.

Seed treatment is a key use of fludioxonil for the control of seed- and soil-borne diseases caused by *Fusarium* spp., *Pythium* spp., *Rhizoctonia* spp. and *Phomopsis* spp. on more than 200 crop species.

Fludioxonil is identified as having a low to medium risk of resistance development. In addition, it is the only active ingredient registered in Canada from the phenylpyrrole group of fungicides. Due to these properties, fludioxonil is not only an important tool for disease management, but is also of value for resistance management. In integrated pest management programs, fludioxonil can be used as a rotational fungicide or as a tank mix partner with other fungicides belonging to different mode of action groups, to delay the development of resistance in pathogens.

Proposed Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk reduction measures to protect human health and the environment. These directions must be followed by law. As a result of the re-evaluation of fludioxonil, the PMRA is proposing further risk reduction measures for product labels:

Environment

- To minimize the potential risk to small birds through the ingestion of treated seeds, hazard statements are required on the product labels, as well as best management practices for the tags of bags containing treated seeds.

- To mitigate the potential exposure of aquatic organisms, mitigation statements and buffer zones have been updated on the product labels.

Next Steps

Before making a final re-evaluation decision on fludioxonil, the PMRA will consider any comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on fludioxonil. The PMRA will then publish a Re-evaluation Decision[2] that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Fludioxonil is a broad-spectrum, contact fungicide with limited curative properties that falls under the Resistance Management Mode of Action Group 12 (phenylpyrroles). Its mode of action involves the inhibition of mitogen-activated protein kinase in the osmotic signal pathway.

Following the re-evaluation announcement for fludioxonil, the registrant of the technical grade active ingredient in Canada indicated continued support for all uses included on the current labels of commercial class end-use products. There are no domestic class end-use products associated with this active ingredient.

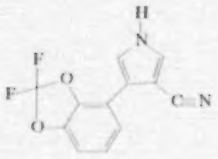
Currently registered products containing fluxional are listed in Appendix 1. All current uses are being supported by the registrant and were, therefore, considered in the re-evaluation of fludioxonil.

The purpose of the re-evaluation is to review existing information on the active ingredient, fludioxonil, and the currently registered fludioxonil technical and commercial class end-use products, to ensure that risk assessments meet current standards.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name		Fludioxonil
Function		Fungicide
Chemical Family		Phenylpyrrole
Chemical name		
1	**International Union of Pure and Applied Chemistry (IUPAC)**	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile
2	**Chemical Abstracts Service (CAS)**	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile
CAS Registry Number		131341-86-1
Molecular Formula		$C_{12}H_6F_2N_2O_2$

Structural Formula	
Molecular Weight	248.2
Registration Number	28399
Purity of the Technical Grade Active Ingredient (%)	98.1

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the *Canada Gazette*, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including Toxic Substances Management Policy (TSMP) Track 1 substances, are not expected to be present in the product.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure at 25°C	3.9×10^{-4} mPa
Ultraviolet (UV) / visible spectrum	$\lambda_{max} = 207$ nm
Solubility in water at 25°C	1.8 mg/L
n-Octanol/water partition coefficient at 25°C	log $K_{ow} = 4.12$ at 25°C $K_{ow} = 13100$
Dissociation constant	$pKa_1 < 0$ $pKa_2 \sim 14.1$

2.3 Description of Registered Fludioxonil Uses

Appendix I lists all fludioxonil products that are registered in Canada.
Use of fludioxonil belongs to the following use-site categories: greenhouse food crops; seed and plant propagation materials food and feed, stored food and feed; terrestrial feed and food crops, outdoor ornamentals and turf.

3.0 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur in animal testing and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers).

3.1 Toxicology Summary

The toxicological database for fludioxonil is considered complete, consisting of the full array of toxicity studies currently required for health hazard assessment purposes. The studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is high and the database is considered adequate to characterize the toxicity of fludioxonil.

Fludioxonil is of low acute toxicity by the oral and dermal route, and low to slightly acute toxicity by the inhalation route. It is non-irritating to the skin, non-sensitizing and causes mild eye irritation.

Absorption and excretion of single oral doses of fludioxonil was rapid and relatively complete in both sexes of rats. The bile was the primary route of elimination, along with urinary excretion.

A short-term dermal study showed no skin irritation in any of the test groups after repeated applications of fludioxonil to the skin of albino rats.

In subchronic and chronic toxicity studies, the target organs were the liver, kidneys and bile duct. Effects of decreased body weight and diarrhea were observed.

Long-term studies provided no evidence of treatment-induced oncogenicity. Fludioxonil is not mutagenic. The developmental toxicity studies and a two-generation study indicated that fludioxonil did not cause malformations and that developmental toxicity and reproductive toxicity occurred only at doses that were maternally toxic as well. For additional details, refer to PMRA Evaluation Report ERC2007-04, *Fludioxonil Scholar 50WP Fungicide*.

3.1.1 *Pest Control Products Act* Hazard Considerations

For assessing risks from potential residues in food or from products used in or around residential areas or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects to take into account potential pre- and post-natal toxicity and completeness of the data with respect to the exposure of, and toxicity to, infants and children. A different factor may be determined to be appropriate on the basis of reliable scientific data.

The toxicity database for fludioxonil is considered complete and adequate for the assessment of risk to infants and children. The potential pre- and post-natal toxicity in rats and potential developmental toxicity in rabbits provided no indication of increased susceptibility of rat or rabbit fetuses to in utero exposure to fludioxonil. There is no indication of increased susceptibility in the offspring compared to parental animals in the reproductive toxicity study. On the basis of this information, the 10-fold *Pest Control Products Act* factor was reduced to one-fold.

3.1.2 Toxicological Endpoints

Appendix II provides an overview of the toxicological endpoints for fludioxonil used in human health risk assessments by the PMRA.

A rat chronic toxicity study was considered the most appropriate to assess chronic dietary exposure, with a no-observed-adverse-effect level (NOAEL) of 3.7 mg/kg bw/day. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied, and the *Pest Control Products Act* factor was reduced to one-fold, resulting in a composite assessment factor of 0.037 mg/kg bw/day. An acute reference dose is not required for fludioxonil, as it is not expected to present an acute dietary hazard.

Occupational exposure is characterized as short- to intermediate-term and is predominantly by the dermal and inhalation routes. An oral route multi-generation reproduction study in rats was considered the most appropriate for short and intermediate exposures, with a NOAEL of 20 mg/kg bw/day. This endpoint is used for both short- and intermediate-term dermal and inhalation exposures.

The rat chronic toxicity study was considered the most appropriate to assess long-term exposure (NOAEL of 3.7 mg/kg bw/day).

Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. The target margin of exposure is 100 for all occupational exposure scenarios.

3.2 Cancer Risk Assessment

A cancer assessment was not required as fludioxonil is not considered to be carcinogenic.

3.3 Dietary Risk Assessment

3.3.1 Residue Chemistry

The metabolism of fludioxonil in treated seeds of rice, wheat, potato, cotton and soybean, in foliar-treated plants of peach, grapes, tomato and green onion as well as in livestock (lactating goat, laying hen) is adequately understood. Analytical methods for determination of fludioxonil residues in treated seed (AG-595, AG-664), harvested crops (AG-597 and AG-597B), grapes and wine (REM-133.01, RES 07/93), grapes and processed commodities (REM133.04), grape must (RES 133.02) and in livestock (AG-616B) were previously reviewed and considered adequate.

Frozen storage stability data are available to support the sample storage conditions. Supervised residue trials are available for a large number of crops to support registered uses.

The residue definition of fludioxonil in Canada under the *Pest Control Products Act* is 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile (parent).

3.3.2 Dietary Exposure and Risk Assessment

In a dietary exposure assessment, the PMRA determines how much of a pesticide residue, including residues in milk and meat, may be ingested with the daily diet (food and drinking water). Exposure to fludioxonil from potentially treated imports is also included in the assessment. These dietary assessments are age-specific and incorporate the different eating habits of the population at various stages of life (infants, children, adolescents, adults and seniors). For example, the assessments take into account differences in children's eating patterns, such as food preferences and the greater consumption of food relative to their body weight when compared to adults.

An acute dietary assessment was not required as there was no relevant endpoint to establish an acute reference dose (ARfD) for fludioxonil.

The chronic dietary risk was calculated by estimating the consumption of different foods and the residue values on those foods. This expected intake of residues was then compared to the acceptable daily intake (ADI). When the expected intake of residues is less than the ADI, then chronic dietary exposure is not of concern. The chronic dietary assessment was refined at the intermediate level using median values from residue field trial data, and experimental processing factors where available. Refined chronic dietary exposure from all supported fludioxonil food uses (import and domestic) for the representative population subgroups ranged from 12.2 – 62.3% of the ADI, and therefore is not of concern.

3.4 Dermal Absorption

The dermal absorption value for fludioxonil is based on an in vivo dermal absorption study in rats. It was determined that a value of 14% is the most appropriate for use in the re-evaluation of fludioxonil.

3.5 Occupational Exposure and Risk Assessment

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies being used to calculate a margin of exposure. This is compared to a target MOE incorporating uncertainty factors protective of the most sensitive subpopulation.

As the toxicological endpoints and MOEs are the same for dermal and inhalation exposure for short and intermediate term durations, it is appropriate to combine the route-specific MOEs to generate a single risk estimate. The dermal and inhalation MOEs were combined into a single MOE. If the combined MOE is greater than the target MOE, then risk mitigation is not required. If it is less than the target MOE, it does not mean that exposure will result in adverse effects. However, a combined MOE, less than the target MOE, requires measures to mitigate (reduce) risk.

3.5.1 Non-seed Treatment Uses

Workers can be exposed to fludioxonil through mixing, loading and applying the pesticide or when entering a treated site to conduct activities, such as scouting, and/or handling of treated crops.

3.5.1.1 Mixer, Loader and Applicator Exposure and Risk Assessment

Mixer, Loader, Applicator (M/L/A) exposure is expected to be mainly via the dermal and inhalation routes. The following scenarios were assessed:

- Mixing, loading of liquid, dry flowables (used for wettable granules), and wettable powders packaged in water soluble packaging
- Groundboom application to canola, spinach, onion, mustard greens, turnip greens, cabbage, carrot, crop group 1B (except sugar beet), field tomato, pepper, strawberry, blueberry (lowbush), beans, lentils, ginseng, outdoor ornamentals and turf (golf courses only)
- Drip irrigation to strawberry
- Irrigation (drench) to outdoor ornamentals
- Aerial application to canola
- Airblast application to blueberry (highbush), Saskatoon berry, grapes, caneberries, and outdoor ornamentals
- Mechanically pressurized handgun, manually pressurized handwand or backpack sprayer application to greenhouse cucumber, greenhouse pepper, greenhouse tomato crop subgroup 8-09A and greenhouse lettuce
- Mechanically pressurized handgun, manually pressurized handwand or backpack sprayer application to outdoor ornamentals and turf (golf courses only)
- Postharvest drench/dip application to pome fruits, stone fruits, cherries, sweet potato and carrot
- Postharvest in-line aqueous spray to carrot, potato and sweet potato

The M/L/A exposure assessment was based on workers wearing the personal protection equipment (PPE) specified on current registered labels, and products being applied at the maximum registered application rate for each crop. The potential dermal and inhalation exposures were estimated using data from the Pesticide Handlers Exposure Database (PHED), Version 1.1.

The occupational risk estimates associated with mixing, loading and applying fludioxonil are not of concern (MOEs > 450; target MOE = 100).

3.5.1.2 Postapplication Exposure and Risk Assessment

The postapplication occupational risk assessment considers dermal exposure to workers entering treated sites to conduct agronomic activities involving contact with the foliage or the treated commodities. There is potential for short- to intermediate-term postapplication exposure (>1 day-6 months) for the majority of crop/activity scenarios, except for greenhouse crops. Postapplication exposure for greenhouse crops is expected to be long-term (> 6 months).

For foliar contact, potential exposure of postapplication workers was estimated using activity-specific transfer coefficients (TCs) and dislodgeable foliar residue (DFR) or transferable turf residue (TTR) values. The DFR and TTR values refer to the amount of residue that can be dislodged or transferred from a surface, such as leaves of a plant. The TC is a measure of the relationship between exposure and DFRs for individuals engaged in a specific activity, and is calculated from data generated in the field. TCs are specific to a given crop and activity combination and reflect standard agricultural work clothing worn by adult workers. Postapplication exposure activities include scouting, irrigating, girding, hand weeding, hand harvesting, and mowing.

There is no specific TC for handling treated fruits/vegetables during sorting/culling activities and manual packaging. The general TC for activities involving greenhouse lettuce is considered appropriate for postapplication activities associated with the postharvest treatment of fruits and vegetables.

The occupational risk estimates associated with postapplication exposure to fludioxonil are not of concern for field crops and turf (MOE > 100, target MOE = 100), for greenhouse uses (MOE >220, target MOE = 100) and for postharvest treatment (MOE >700, target MOE = 100).

3.5.1.3 Conclusion

The risk assessment indicated that there is no concern for both occupational M/L/A and postapplication exposure for all non-seed treatment uses. All required mitigation measures are already on product labels. Therefore, no additional risk reduction measures are proposed.

3.5.2 Seed Treatment Uses

Workers can be exposed to fludioxonil through mixing, loading or applying the pesticide, or when planting commercially treated seed.

3.5.2.1 Mixer, Loader and Applicator Exposure and Risk Assessment

There are potential exposures to mixers, loaders, and applicators. The following seed treatment scenarios were assessed:

- Commercial mixing, loading, and applying liquid treatment to cereals, corn, oilseeds, legumes, vegetables, grasses, non-grass feed, peanuts, plants, flowers, herbs and spices (activities may include treating, bagging, stacking, tagging, and cleaning)
- Planting of commercially treated seed (activities may include loading)
- On-farm mixing, loading and applying liquid seed treatment to legumes, herbs and spices and planting treated seed
- On-farm mixing, loading and applying dust as a potato seed piece treatment and planting treated potato seed
- Commercial and on-farm mixing, loading and applying liquid potato seed piece treatment and planting treated potato seed

Fludioxonil is registered for seed and potato seed piece treatments, which may occur both on-farm and in commercial facilities. Potato seed piece treatments using dust formulations were assessed as on-farm treatment only, as the registrant confirmed that commercial treatment of potato seed pieces does not occur in Canada. Treatment of small seeds by pelletization was not assessed, as no data were available to assess this method.

PHED scenarios were not considered to be representative of exposure to workers treating or handling treated seed. Surrogate exposure studies representative of seed treatment activities were used to estimate exposure, as these are the best available data. See Appendix III, Table 1 for a description of the studies and unit exposure values used in this assessment.

Exposure to workers treating and/or planting seed and potato seed pieces is expected to be short- to intermediate-term (<30 days to <6 months) in duration. On-farm treatment and planting generally occurs over a period of a few days to up to a couple of weeks, during spring planting. Commercial seed treatment can occur for short to extended periods of time in the spring and fall, depending on the site and crop seed treated. During the operation of commercial seed treatment facilities, fludioxonil would typically be used intermittently, as numerous seed types and treatment regimens will be used.

Calculated MOEs exceed the combined target MOE for all crops treated on-farm and in commercial treatment facilities with baseline PPE, and are not of concern. As such, no additional mitigation measures are required for these scenarios. The results of the risk assessment are summarized in Appendix III, Table 2.

The comparisons of unit exposure values from commercial mobile treaters (commercial applicators for treating of seeds conducted outside of commercial facilities) and commercial seed treatment facilities (that have open pour transfer and closed treatment equipment) suggest that exposures from commercial mobile treaters may be similar to those from commercial seed treatment facilities. As such, it was determined that the risk assessment conducted for fludioxonil in commercial seed treatment facilities can be applied to commercial mobile treaters.

3.5.2.2 Postapplication Exposure and Risk Assessment

Farmers planting treated seed have the potential for short- to intermediate-term duration of exposure. Only farmers loading and planting commercially treated seeds from bags will be assessed in this section, as additional exposure from loading seeds from bags is expected. On-farm seed treatment exposure studies include planting; therefore, a separate planting exposure assessment for seed treated on-farm is not required. Farmers planting commercially treated seeds delivered in bulk (not bagged) are not anticipated to have the additional exposure from loading bagged seeds, and therefore; their exposure is considered to be addressed by the on-farm seed treatment and planting exposure risk assessment.

Calculated MOEs exceed the target MOE for planting all seeds treated with fludioxonil, using baseline PPE, and are not of concern. It should be noted that the study used to assess this scenario (PMRA #1571553) was conducted using a closed cab planter. However, it was determined that the use of closed cabs is not required, as the calculated MOEs exceed the target MOE by over an order of magnitude. Thus, there is a sufficient margin to address the additional exposure expected from open cab. The results of the risk assessment are summarized in Appendix III, Table 3.

3.6 Non-occupational and Residential Exposure and Risk Assessment

3.6.1 Residential Exposure and Risk

No residential M/LA risk assessment was required for fludioxonil, as there are no registered domestic products containing fludioxonil in Canada and no expected residential uses of commercial products.

3.6.1.1 Handling Treated Ornamentals

There is potential dermal exposure to people handling commercially treated ornamentals at home or public areas. The postapplication exposure for handling treated ornamentals is not of concern (MOE >1500, target MOE = 100).

3.6.1.2 Golfers

There is potential for short- to intermediate-term exposure to golfers exposed to freshly treated turf. Exposure to golfers was estimated using default peak value and TCs representative of typical golfing activities for adult, youth and child golfers. The estimated exposure for golfers in contact with treated turf is not of concern (MOE > 4600, target MOE = 100).

3.6.1.3 Bystanders

Potential for bystander exposure is considered minimal and is expected to be significantly less than exposures estimated for workers. Based on the worker risk assessment, bystander exposure is not of concern.

3.7 Aggregate Exposure and Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other nonoccupational sources as well as from all known or plausible exposure routes (oral, dermal and inhalation).

Aggregate exposure from food and drinking water is considered acceptable and below the level of concern for all population subgroups. The highest exposed population subgroup was children three to five years old (< 64% of ADI).

Based on the exposure estimates from food and drinking water (<64% of the ADI), from handling commercially treated ornamentals (MOE > 1500) and from golfers in contact with freshly treated turf (MOE> 4600), it is not expected that aggregate exposure would result in a risk of concern.

3.8 Cumulative Exposure and Risk Assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. For the current re-evaluation, the PMRA did not identify a common mechanism of toxicity for fludioxonil and other pest control products. Therefore, there is no requirement for a cumulative assessment at this time.

4.0 Environment

4.1 Fate and Behaviour in the Environment

Fludioxonil is of low solubility in water. Based on its vapour pressure and Henry's law constant, fludioxonil is expected to have a low potential for volatilization. Fludioxonil is stable to hydrolysis at pH 5, 7 and 9. Its phototransformation half-life is 15 days on soil and 0.86 to 11.5 days in water. SYN 545245 and CGA 339833 are the major phototransformation products on soil. Only minor transformation products are formed in water.

Fludioxonil is persistent in soil under aerobic conditions (half-life from 143 to 494 days) and stable under anaerobic soil conditions. Fludioxonil is expected to carry over to the following growing season. An environmental hazard statement indicating persistence/carryover, and a recommended best practice (products containing fludioxonil not to be used in areas treated with fludioxonil during the previous season) are currently included on product labels registered for field crop uses.

In water/sediment systems, fludioxonil rapidly moves from the water column into the sediment phase, where it remains strongly bound. Fludioxonil is persistent in aerobic aquatic systems (water and sediments), with half-lives of 737 and 643 days in pond and river systems, respectively. Fludioxonil is stable under anaerobic conditions in flooded soil and in sediments.

Soil organic carbon-water partition coefficient (K_{oc}) values for fludioxonil ranged from 11,462 to 363,311 in sand, sandy loam, sandy silt, sandy silt loam and silt clay loam soils, indicating that fludioxonil is immobile in soils.

Although the *n*-octanol/water partition coefficient (log K_{ow}) of fludioxonil (4.12) denotes a potential for bioaccumulation, a bioaccumulation study in fish indicated that fludioxonil is not expected to bioaccumulate in fish (bioconcentration factor of 366).

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur.

Estimated environmental concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rates, chemical properties and environmental fate properties, including the dissipation of the pesticide between applications.

Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the RQ is then compared to the level of concern (LOC). If the screening level RQ is below the LOC, the risk is considered negligible and no further risk characterization is necessary. If the screening level RQ is equal to or greater than the LOC, then a refined risk assessment is performed to further characterize the risk.

A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Turf

EECs in soil, water and food sources potentially ingested by wild birds and mammals were generated based on the highest registered application rate on turf (750 g a.i./ha, 3 applications per year, 7-day intervals).

Birds and mammals:
At the highest application rate on turf, the LOC was exceeded (on field) for a number of small, medium and large sized birds and small mammals. A precautionary statement is included on the corresponding product label. RQs (off field) did not exceed the LOC when taking into account the 6% field sprayer drift.

Terrestrial organisms:
Bees and earthworms are not at risk from the use of fludioxonil on turf. The LOC was slightly exceeded for vascular plants at the highest application rate on turf. Mitigation, in the form of a one metre terrestrial buffer zone, is indicated on product labels.

Aquatic organisms:
A risk to aquatic organisms was identified at the screening level. Refined assessments were conducted for both spray drift and runoff. In a number of cases, RQs exceeded the LOC for both spray drift ($RQ \leq 4.7$) and runoff ($RQ \leq 1.3$). Aquatic buffer zones and a precautionary label statement are included on current labels for turf uses to minimize risks to aquatic organisms.

4.2.2 Field Crops

EECs in soil, water and food sources potentially ingested by wild birds and mammals were generated based on the highest registered application rate on field crops (244 g a.i./ha, 3 applications per year, 7-day intervals).

Terrestrial organisms:
Bees, earthworms and terrestrial vascular plants are not at risk from the use of fludioxonil on field crops.

The acute avian and small mammal LD_{50} are > 50 mg/kg bw (>2000 mg/kg bw and >5000 mg/kg bw for birds and mammals, respectively). RQs for birds and mammals did not exceed the LOC when considering mean residues, with the exception of small insectivorous birds. However, the assessment assumed that birds and mammals consume 100% of a given food item and all ingested food is contaminated. With a varied diet, the exposure is expected to be lower than predicted in the risk assessment and the risk posed to small insectivorous birds from field crop use is considered to be acceptable.

Aquatic organisms:
The LOC was not exceeded for aquatic organisms, with the exception of amphibians, which may be at risk due to fludioxonil use on field crops. A precautionary label statement and mitigation in the form of aquatic buffer zones are included on current labels, which reduce risk to amphibians.

Updated buffer zones are listed in Appendix IV

4.2.3 Seed Treatment Uses

A screening level risk assessment conducted for birds and mammals was based on a maximum application rate of 5.2 g a.i./100 kg seed.

Birds are not at risk on an acute basis, but the LOC based on reproduction was marginally exceeded for small sized birds. In addition, spilled seeds may be consumed by small birds in sufficient quantities to result in exposure exceeding the LOC. Consequently, the following precautionary label statement is proposed for seed treatment products:

"Treated seed is toxic to small birds. Any spilled or exposed seeds must be incorporated into the soil or otherwise cleaned up from the soil or other surfaces".

This statement is not proposed for use on potato seed pieces, as small birds are not expected to eat potatoes.

4.2.4 Greenhouse Uses and Postharvest Treatment

Fludioxonil is registered for use on greenhouse crops and as a postharvest treatment on a number of crops. Release to the environment from the use of fludioxonil for control of diseases in greenhouse crops and postharvest storage diseases is expected to be negligible. No additional mitigation measures are proposed for these uses.

5.0 Value

Fludioxonil is registered as a seed treatment and as a foliar spray for control of a broad range of fungal diseases on a large number of food and feed crops. It is also registered as a postharvest treatment for control of postharvest diseases that lead to spoilage of stone fruits, pome fruits, sweet potatoes, potatoes and carrots in storage.

Seed treatment is a key use of fludioxonil for the control of various seed- and soil-borne diseases, including the seedling disease complex (seed decay, damping-off and seedling blight) caused by *Fusarium* spp., *Pythium* spp., *Rhizoctonia* spp. and *Phomosis* spp. on more than 200 crop species. A substantial proportion of canola, chickpeas, corn, dry beans, soybeans, lentils and field peas in Canada are treated with fludioxonil as a seed treatment. As a potato seed piece treatment, fludioxonil also provides effective control of seed piece decay caused by black scurf, silver scurf and fusarium dry rot. It is also important for the control of pink and gray snow moulds on turf as some other active ingredients for this use have been phased out.

Due to its broad spectrum properties, fludioxonil is an important tool for resistance management in integrated pest management programs, where it can be used as a rotational fungicide or as a tank mix partner with other fungicides belonging to different mode of action groups, to delay the development of resistance in pathogens. Thus, the effective life of both fludioxonil and other mode of action fungicides can be enhanced.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bioaccumulative, primarily a result of human activity, and toxic, as defined by the *Canadian Environmental Protection Act*].

During the re-evaluation process, fludioxonil was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, and evaluated against the Track 1 criteria. The PMRA has reached the following conclusion:

- Fludioxonil is found to persist in water/sediment (half-life of 647 to 737 days) and soil (half-life of 494 days). The half-life in soil and water is above the TSMP Track 1 criteria (half-life in water or soil $\geq$ 182 days or in sediment > 365 days), therefore it is concluded that fludioxonil does meet the criteria for persistence.

- The log K_{ow} of 4.12 for fludioxonil is below the TSMP Track 1 criterion (log $K_{ow} \geq 5$). The bioconcentration factor (BCF) for fludioxonil is 366, below the TSMP Track 1 criterion (BCF $\geq$ 5000). On this basis, it is concluded that fludioxonil does not meet the criteria for bioaccumulation.

- Fludioxonil does not meet all Track 1 criteria and therefore is not considered a Track 1 substance.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the re-evaluation of fludioxonil, contaminants in the technical grade active ingredient were compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[3]. The list is used as described in the PMRA Notice of Intent NOI2005-01[4] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02[5], and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusion:

- Technical grade fludioxonil does not contain any contaminants of health or environmental concern identified in the *Canada Gazette*.

7.0 Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents to the PMRA, including adverse effects to Canadian health and the environment within a set timeframe. As of 23 January 2015, the PMRA had received 19 human and 17 domestic animal incidents involving fludioxonil.

Of the 19 human cases, the symptoms reported in two moderate and eight minor cases were determined to have some degree of association with the reported exposure. In two minor cases involving children between the ages of six and 12 years, exposure to fludioxonil occurred as a result of contact with treated seeds or seed dust. In all other cases, activities leading to exposure occurred when individuals handled seeds treated with a pesticide containing fludioxonil. Overall, dermal effects such as itchy skin and rash were commonly reported in these incidents.

Animal types commonly reported in domestic animal incidents were cows and dogs. Incidents involving death mainly occurred in the United States and were reported in cows. Canadian incidents generally involved dogs and were either moderate or minor in severity. Overall, the commonly outlined symptoms in animals were gastrointestinal effects like vomiting and diarrhea and general effects like dehydration. The reported exposure scenario generally involved ingestion of seeds treated with fludioxonil along with other active ingredients.

Incidents involving fludioxonil were considered in this review and as a result, additional statements to improve product labels are described in Appendix IV.

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3 *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

4 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under the New Pest Control Products Act.

5 DIR2006-02, *PMRA Formulants Policy*.

8.0 Organisation for Economic Co-operation and Development Status of Fludioxonil

Canada is a member of the Organisation for Economic Co-operation and Development (OECD), which groups 34 member countries and provides governments with a setting in which to discuss, develop and perfect economic and social policies.

As part of the re-evaluation of an active ingredient, the PMRA takes into consideration recent developments and new information on the status of an active ingredient in other jurisdictions, including OECD member countries. In particular, decisions by an OECD member country to prohibit all uses of an active ingredient for health or environmental reasons are considered for relevance to the Canadian situation.

Fludioxonil is currently acceptable for use in other OECD countries, including the United States, Australia and European Union Member States. As of 12 March 2015, no decision by an OECD member country to prohibit all uses of fludioxonil for health or environmental reasons has been identified.

9.0 Proposed Re-evaluation Decision

The PMRA is proposing that products containing fludioxonil are acceptable for continued registration with the implementation of the proposed risk reduction measures. The measures are proposed to protect human health and the environment. .

Since there was insufficient data available to conduct risk assessments for pelleting small seeds using a liquid formulation and for commercial treatment of potato seed pieces using a dust formulation. PMRA is proposing label wording to clarify that these uses are not included. The proposed mitigation measures are presented in Appendix IV. No additional data are being requested at this time.

10.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2012-02, *Re-evaluation Program Cyclical Re-evaluation*, and DACO tables can be found on the Pesticides and Pest Management portion of Health Canada's website. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca

The federal TSMP is available through Environment Canada's website.

List of Abbreviations

µg	microgram
ADI	acceptable daily intake
a.i.	active ingredient
ARfD	acute reference dose
bw	body weight
CAF	composite assessment factor
CAS	chemical abstracts service
cm	centimetres
DA	dermal absorption
DACO	data code
DFR	dislodgeable foliar residue
EEC	estimated environmental concentration
g	gram
ha	hectare(s)
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon-water partition coefficient
K_{ow}	octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOC	level of concern
M	metre
mg	milligram
M/L/A	mixer/loader/applicator
MOE	margin of exposure
mPa	millipascal
MRL	maximum residue limit
N/A	not applicable
NIOSH	National Institute of Occupational Safety and Health
NOAEL	no observed adverse effect level
NOEL	no observed effect level
OECD	Organisation for Economic Co-operation and Development
pH	-log10 hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
REI	restricted entry interval
RQ	risk quotient
TC	transfer coefficient
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
TTR	turf transferable residue
UV	ultraviolet

Appendix I Fludioxonil Products Registered in Canada as of 1 December 2014

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
24731[1]	TGAI	Syngenta Canada Inc.	Fludioxonil Technical Fungicide	Dust	97.6%
28399	TGAI	Syngenta Canada Inc.	Fludioxonil Technical	Dust	98.1%
26637	Commercial	Syngenta Canada Inc.	Helix Liquid Seed Treatment	Suspension	0.13%[2]
26638	Commercial	Syngenta Canada Inc.	Helix XTra Seed Treatment	Suspension	0.13%[2]
26647	Commercial	Syngenta Canada Inc.	Maxim PSP Potato Seed Protectant	Dust	0.5%
27001	Commercial	Syngenta Canada Inc.	Maxim 480 FS Colourless Seed Treatment Fungicide	Solution	40%
27071	Commercial	Syngenta Canada Inc.	Maxim XL Seed Treatment Fungicide	Suspension	21%[2]
27577	Commercial	Syngenta Canada Inc.	Apron Maxx RTA Seed Treatment Fungicide	Suspension	0.73%[2]
27650	Commercial	Syngenta Canada Inc.	Tribune Seed Treatment Fungicide	Suspension	0.17%[2]
27965	Commercial	Syngenta Canada Inc.	Maxim MZ PSP	Dust	0.5%[2]
28189	Commercial	Syngenta Canada Inc.	Switch 62.5 WG Fungicide	Wettable granule	25.0%[2]
28568	Commercial	Syngenta Canada Inc.	Scholar 50WP Fungicide	Wettable powder	50%
28817	Commercial	Syngenta Canada Inc.	Apron Maxx RFC Seed Treatment Fungicide	Suspension	2.31%[2]
28821	Commercial	Syngenta Canada Inc.	Cruiser Maxx Beans Seed Treatment	Suspension	1.12%[2]
28861	Commercial	Syngenta Canada Inc.	Instrata Fungicide	Suspension	14.5 g/[2]
29110	Commercial	Syngenta Canada Inc.	Maxim Liquid PSP	Solution	40.3%
29528	Commercial	Syngenta Canada Inc.	Scholar 230SC Fungicide	Suspension	230 g/L
29648	Commercial	Syngenta Canada Inc.	Astound Fungicide	Wettable granule	25.0%[2]
29814	Commercial	Syngenta Canada Inc.	Proseed Seed Treatment	Solution	40.3%
29871	Commercial	Syngenta Canada Inc.	Maxim Quattro Seed Treatment	Suspension	3.32%[2]
30185	Commercial	Syngenta Canada Inc.	Cyproflu Fungicide	Wettable granule	25.0%[2]
30388	Commercial	Syngenta Canada Inc.	A18046A Seed Treatment	Suspension	12.9 g/L[2]

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
30599	Commercial	Syngenta Canada Inc.	Maxim D	Suspension	19.4 g/L[2]
30627	Commercial	Syngenta Canada Inc.	Apron Advance Seed Treatment	Suspension	25 g/L[2]
30763	Commercial	Syngenta Canada Inc.	Palladium Fungicide	Wettable granule	25.0%[1]
31024	Commercial	Syngenta Canada Inc.	Cruiser Maxx Potato Extreme	Suspension	62.5 g/L[2]
31050	Commercial	Syngenta Canada Inc.	Stadium Fungicide	Suspension	143 g/L[2]
31408	Commercial	Syngenta Canada Inc.	Vibrance Quattro	Suspension	7.6 g/L[2]
31453	Commercial	Syngenta Canada Inc.	Cruiser Vibrance Quattro	Suspension	7.7 g/L[2]
31454	Commercial	Syngenta Canada Inc.	Helix Vibrance	Suspension	1.7 g/L[2]
31528	Commercial	Syngenta Canada Inc.	Medallion Fungicide	Suspension	125 g/L

[1] discontinued on 20 February 2015
[2] co-formulated with other active ingredient(s), which are not listed in the table.

Appendix II Toxicological Endpoints for Fludioxonil Health Risk Assessments

Exposure Scenario	Point of departure[1] (mg/kg bw/day)	Study	Endpoint	CAF[2] or target MOE[3]
Chronic Dietary	**NOAEL**= 3.7	Two-year carcinogenicity studies in rats	Increased incidence of liver lesions (degeneration/atrophy/necrosis/inflammation) in females	100
	ADI = 0.037 mg/kg bw/day, uncertainty factor = 100			
Acute Dietary, general population	**ARfD:** N/A (Not required, no relevant acute endpoint identified)			
Short and intermediate-term dermal[4]	20	Two-generation reproduction in rats	Decreased bodyweights and bodyweight gains in females	100
Short and intermediate-term inhalation	20	Two-generation reproduction in rats	Decreased body weights and body-weight-gains in females	100
Long-term Dermal[4]	3.7	Two-year carcinogenicity studies in rats	Increased incidence of liver lesions(degeneration/atrophy/necrosis/inflammation) in females	100
Cancer	N/A (q_1* not established)			

[1] NOAEL = no observed adverse effect level; ADI = acceptable daily intake; ARfD = acute reference dose

[2] CAF (composite assessment factor) refers to a total of uncertainty and *Pest Control Products Act* factors for dietary assessments

[3] target MOE (margin of exposure) for occupational assessments

[4] A dermal absorption factor of 14% was used in a route-to-route extrapolation.

Appendix III Seed Treatment Mixer/Loader/Applicator and Postapplication Risk Assessment

Table 1 Seed and Potato Seed Piece Treatment Exposure Studies

Study Summary	PPE	Tasks	Unit Exposure (µg/kg a.i.)[1]	
			Dermal	Inhalation
Commercial Liquid Application (cereals, corn, herbs and spices, grasses, non-grass animal feed, oilseeds, peanuts, plants and flowers, vegetables)				
Dean, 1993[2] (PMRA #1135469). **Exposure of Workers to Triadimenol During Treatment of Grain Seeds with Baytan 312FS. Sponsored by Miles Inc. Unpublished.** The study measured exposure of workers during commercial seed treatment of winter wheat with Baytan 312 FS, a liquid formulation of triadimenol, at three treatment facilities (large, medium and small) in Ontario, Canada. Workers were monitored for 3-3.5 hours at each facility for a total of 55 half-day replicates. The maximum amount of active ingredient handled per replicate was 21.9 kg. Dermal exposure was estimated using patch dosimeters and hand washes. Inhalation exposure was measured using personal air sampling pumps.	Closed M/L, single layer + gloves	Treater/Bagger (n=16)	357.42	118.76
		Stacker/Tagger (n=30)	61.68	34.36
		Forklift Operator (n=4)	12.02	1.21
Krolski, 2006[3](PMRA #1335563). **Gaucho 480 SC – Worker Exposure During On-farm and Commercial Seed Treatment of Cereals. Sponsored by Bayer CropScience. Unpublished.** This study was designed to estimate exposure to imidacloprid during normal commercial and on-farm treating of wheat seed. Sixteen trials were performed to assess the exposure of agricultural workers during the treatment and planting of wheat grain seeds. Twelve trials were conducted with on-farm treater/planters and four were conducted with commercial applicators. Dermal exposure was estimated using while body dosimeters, hand rinses and face/neck wipes. Inhalation exposure was measured using personal air sampling pumps.	Open M/L, single layer + gloves	Mixer, loader, applicator	265.7 (90^{th} percentile)	2.47 (90^{th} percentile)

Study Summary	PPE	Tasks	Unit Exposure (µg/kg a.i.)[1]	
			Dermal	Inhalation
Wilson, 2009 (PMRA #1772278). **Jockey - Determination of Operator Exposure During Cereal Seed Treatment with Jockey Fungicide in Germany, United Kingdom and France. AgroChemex International Ltd. Unpublished.** The study was performed to determine potential dermal and inhalation exposure to fluquinconazole and prochloraz during a typical day's activities associated with mixing, loading, bagging of treated seed (wheat) and cleaning of seed treatment equipment at a commercial seed treatment facility using batch or continuous flow seed treatment equipment. The operator exposure study was conducted with 39 operators at 11 sites. Eight operators were monitored for exposure during procedures associated with the cleaning of the treatment chamber. Nine operators were monitored for the exposure during procedures associated with mixing, loading and calibrating. Dermal exposure was estimated using while body dosimeters, hand rinses and face/neck wipes. Inhalation exposure was measured using personal air sampling pumps.	Closed M/L, chemical resistant coveralls + CR gloves	Treater	0.88	0.16
		Cleaner	18.46 µg/g a.i./100 kg seed	0.64 µg/g a.i./100 kg seed
On-Farm Liquid Application (legumes, herbs and spices)				
Purdy, 1999 (PMRA #1191375). **On-farm Operator Exposure Study with Dividend 36FS Seed Treatment on Wheat. Sponsored by Novartis Crop Protection Canada Inc. Unpublished.** Sixteen replicates of on-farm seed treatment procedures were monitored for potential exposure to workers treating seed and handling treated seed for planting (for example, loading, calibration, planting, repair, and clean-up). The study was conducted at 15 different farms in Manitoba using the Canadian liquid formulation of Dividend 36FS. Dermal exposure was monitored with whole body dosimeters, face/neck wipes and hand washes. Inhalation was monitored using personal air sampling pumps.	Auger M/L, open cab, single later + gloves + hat	Mixing, loading, treating, planting (n=16)	407.34	223.03

Study Summary	PPE	Tasks	Unit Exposure (µg/kg a.i.)[1]	
			Dermal	Inhalation
Planting Commercially Treated Seed (cereals, corn, herbs and spices, grasses, non-grass animal feed, oilseeds, peanuts, plants and flowers, vegetables)				
Zietz, 2007[1] (PMRA #1571553). **Determination of Operator Exposure to Imidacloprid During Loading/Sowing of Gaucho Treated Maize Seeds under Realistic Field Conditions in Germany and Italy. Sponsored by SeedTropex Task Force. Unpublished.** The study measured exposure of 16 workers loading and planting corn seed treated with Gaucho in Germany and Italy. Workers were monitored for approximately six to eight hours, handled an average of 1.20 kg of active ingredient and planted seed to 5.5 to 40.2 ha of land. Dermal exposure was measured using whole body dosimeters, face/neck wipes and hand wash samples. Inhalation exposure was measured with personal air sampling pumps.	Manual loading, closed cab, single layer + gloves	Loading, planting (n=15)	1515	82.83
Potato Seed Piece Treatment – Powder Application On-farm				
Maasfeld, 2001 (PMRA #1525896). **Determination of Exposure to Pencycuron During Loading and Application of Moncereen Droogontsmetter (Monceren DS 12.5) in Potato Fields. Sponsored by Bayer. Unpublished.** Five farmers were monitored for worker exposure to pencycuron when applying the product formulated as a powder to potato seed pieces and planting treated potatoes seeds. Approximately 15-30 kg of product was handled and the area treated varied from 3.5 ha to 5.5 ha. Work days ranged from 5.75 to 8.5 hours. Dermal exposure was measured with whole body dosimeter and cotton gloves. Inhalation exposure was determined by the use of a personal air sampling pump.	Open M/L, closed cab, single layer, work jacket + gloves	All positions including planting (n=5)	2860	77.6
Potato Seed Piece Treatment – Liquid Application Commercial and On-farm				
Mackie, 2006 (PMRA 1372835). **Admire 240F - Determination of Dermal**	Open M/L, single layer + gloves	Treater	291	11.5
		Cutter/Sorter	NM	18.0

Study Summary	PPE	Tasks	Unit Exposure (µg/kg a.i.)[1]	
			Dermal	Inhalation
and Inhalation Exposure of Workers During On-farm Seed Piece Treatment of Potatoes. Sponsored by Bayer. Unpublished. Sixteen worker replicate trials were conducted to generate dermal and inhalation exposure data for workers treating potato seed pieces using Admire 240F, a liquid flowable formulation containing the active ingredient imidacloprid. Mixing, loading and treating activities were monitored at eleven different potato treating cooperator locations in southern Manitoba. Planter exposure was not monitored. Actual monitoring duration ranged from 5.75 hours to just over 10 hours. The amount of imidacloprid handled per monitoring period ranged from 3.63 to 12.72 kg. Total dermal exposure to imidacloprid was measured using whole body dosimeters, hand washes, and face/neck wipes. Inhalation exposure was measured by means of a personal air sampling pumps.		All tasks	291	18.0

PPE = Personal protective equipment, M/L = mixing/loading, NM = not measured

[1] Arithmetic mean from surrogate exposure studies, unless otherwise specified.

[2] It was determined that the Dean (1993) study can only be used to support closed mixing and loading in commercial seed treatment facilities. The rationale is discussed in a memorandum dated January 2012.

[3] The 90th percentile was used for this study. Although not specified in the original study review, the major study limitation of small sample size (n=4) was recently discussed and documented in a level D review (Sub. No. 2009-0949) where it was decided to use the 90th percentile to address this limitation.

[4] Revised dermal unit exposure values for the Zietz (2007) study were used in this assessment as a result of registrant comments relating to sub. No. 2009-4506. The revised analysis is captured in a PMRA memorandum dated 6 September 2012.

Table 2 Fludioxonil Seed and Potato Seed Piece Treatment Short- to Intermediate-term Exposure and Risk Assessment

Crop[1]	Formulation[2]	Activity[3]	Application Rate (g a.i./ kg seed)[4]	Throughput (kg seed/day)[4]	MOE		Combined MOE[7] Target = 100
					Dermal[5] Target = 100	Inhalation[6] Target = 100	
Commercial Seed Treatment							
PPE: Long sleeved shirt, long pants and chemical-resistant gloves; Open mixing/loading							
Cereals (except corn), grasses, herbs and spices, non-grass animal feed, plants and flowers[8,9]	Liquid	Mixer/Loader/Applicator	0.052	325700	2600	38000	2500
Corn[9]			0.050	125000	7100	100000	6600
Legumes[9]			0.052	63000	14000	200000	13000
Oilseeds[9]			0.050	67000	13000	190000	12000

Crop[1]	Formulation[2]	Activity[3]	Application Rate (g a.i./ kg seed)[4]	Throughput (kg seed/day)[4]	MOE		Combined MOE[7] Target = 100
					Dermal[5] Target = 100	Inhalation[6] Target = 100	
Peanuts[9]			0.050	54400	16000	240000	15000
Vegetables[9]			0.052	39900	21000	310000	20000
PPE: Long sleeved shirt, long pants and chemical-resistant gloves; Closed mixing/loading; Closed transfer							
Cereals (except corn), grasses, herbs and spices, non-grass animal feed, plants and flowers[8,9]	Liquid	Treater/Bagger	0.052	325700	1900	800	560
		Stacker/Tagger	0.052	325700	11000	2700	2200
		Forklift Operator	0.052	325700	58000	78000	33000
Corn[10]		Treater/Bagger	0.050	125000	5300	2200	1500
		Stacker/Tagger	0.050	125000	31000	7500	6000
		Forklift Operator	0.050	125000	160000	210000	90000
Legumes[10]		Treater/Bagger	0.052	63000	10000	4100	2900
		Stacker/Tagger	0.052	63000	58000	14000	11000
		Forklift Operator	0.052	63000	300000	400000	170000
Oilseeds[10]		Treater/Bagger	0.050	67000	9800	4000	2900
		Stacker/Tagger	0.050	67000	57000	14000	11000
		Forklift Operator	0.050	67000	290000	390000	170000
Peanuts[10]		Treater/Bagger	0.050	54400	12000	5000	3500
		Stacker/Tagger	0.050	54400	70000	17000	14000
		Forklift Operator	0.050	54400	360000	490000	210000
Vegetables[10]		Treater/Bagger	0.052	39900	16000	6500	4600
		Stacker/Tagger	0.052	39900	92000	22000	18000
		Forklift Operator	0.052	39900	470000	640000	270000
PPE: Chemical resistant coveralls, long-sleeved shirt, long pants, chemical-resistant gloves							
Cereals (except corn), grasses, herbs and spices, non-grass animal feed, plants and flowers[8,9]	Liquid	Treater + Cleaner[15]	0.052	325700	110000	440000	86000
Corn[9]			0.050	125000	120000	490000	96000
Legumes[9]			0.052	63000	120000	470000	95000
Oilseeds[9]			0.050	67000	120000	490000	99000
Peanuts[9]			0.050	54400	120000	490000	99000
Vegetables[9]			0.052	39900	120000	480000	96000

Crop[1]	Formulation[2]	Activity[3]	Application Rate (g a.i./ kg seed)[4]	Throughput (kg seed/day)[4]	MOE		Combined MOE[7] Target = 100
					Dermal[5] Target = 100	Inhalation[6] Target = 100	
On-farm Seed Treatment							
PPE: Long sleeved shirt, long pants, chemical-resistant gloves; Open mixing/loading; Open cab planter							
Legumes[11]	Liquid	All tasks (loading, treating, planting)	0.025	12000	96000	24000	19000
Herbs and spices[11,14]			0.052	1960	280000	70000	56000
Potato Seed Piece Treatment – On-farm							
PPE: Long sleeved shirt, long pants, chemical-resistant gloves; Open mixing/loading							
Potato Seed Pieces[13]	Liquid	Treater	0.025	290400	5600	19000	4300
		Cutter/Sorter	0.025	290400	NM	12000	NA
		Treater/Cutter/Sorter	0.025	290400	5600	12000	3800
Potato Seed Pieces[12]	Dust	All tasks including planting	0.025	178000	900	4600	770

NM = not measured; NA = Not applicable; MOE = margin of exposure; NOAEL = No observed adverse effects level

[1] Crops were designated into crop seed categories for assessment purposes as specific data were not available for all crops. Crops were categorized based on similar use patterns such as comparable rates of application and amount of seed handled or planted per day and seed type. The highest values within each category were selected for use in the assessment.

[2] Liquid formulation includes solutions and suspensions. Dust = Dust or Powder

[3] Activities are based on what was monitored in the surrogate exposure study.

[4] Maximum application rates were used in the assessment.

[5] Where MOE = margin of exposure; MOE = NOAEL/Exposure, based on the short- to intermediate-term dermal NOAEL of 20 mg/kg bw/day from oral reproductive toxicity study and dermal absorption of 14%. Exposure (mg/kg bw/day) = (Unit exposure (µg/kg a.i.) × Application Rate (kg a.i./kg seed) × Throughput (kg seed/day) × DA (14%) × 0.001 mg/µg/BW (80 kg)

[6] Where MOE = margin of exposure; MOE = NOAEL/Exposure, based on the short- to intermediate-term inhalation NOAEL of 20 mg/kg bw/ day from oral reproductive toxicity study and no respirator. Exposure (mg/kg bw/day) = (Unit exposure (µg/kg a.i.) × Application Rate (kg a.i./kg seed) × Throughput (kg seed/day) × 0.001 mg/µg/BW (80 kg)

[7] Calculated using the following equation: Combined MOE = 1/(1/dermal MOE + 1/inhalation MOE)

[8] There were insufficient data for grasses, non-grass animal feeds, herbs and spices; cereals were used as a surrogate to estimate exposure as they had a very high throughput, which is not expected to underestimate the throughput of those crops where data were not available.

[9] The Krolski (2006) study was used. Bagging and cleaning were not monitored in this study.

[10] The Dean (1993) study was used.

[11] The Purdy (1999) study was used. Cleaning was not monitored in this study. See Section 3.2 for more information.

[12] The Maasfield (2001) study was used.

[13] The Mackie (2006) study was used.

[14] Throughput value based on data submitted by the registrant for cumin (Sub. No. 2012-1665).

[15] The Wilson (2009) study was used to assess cleaning activities. Treater and cleaner data exposures were combined (as per PMRA# 2085930, Sub. No. 2015-1529) as cleaner exposure was only monitored for 9-33 minutes in the study, and it is likely that these workers could also treat seed in the shift.

Table 3 Planting Exposure and Risk Assessment for Commercially Treated and Bagged Seed[1]

Crop[2]	Formulation[3]	Application Rate (g a.i./ kg seed)[4]	Planting Rate (kg seed/day)[4]	MOE		Combined MOE[7] Target = 100
				Dermal[5] Target = 100	Inhalation[6] Target = 100	
PPE: Long sleeved shirt, long pants and chemical-resistant gloves; Open loading; Closed cab planter[10]						
Cereals (except corn)[8,9]	Liquid	0.052	13500	11000	28000	7900
Corn[9]	Liquid	0.050	1350	120000	290000	82000
Grass, non-grass-animal feed, plants and flowers, vegetables[9]	Liquid	0.052	1810	83000	200000	59000
Herbs and spices[9]	Liquid	0.052	1960[10]	76000	190000	54000
Legumes[9]	Liquid	0.052	19000	7900	20000	5600
Oilseeds[9]	Liquid	0.050	9000	17000	43000	12000
Peanuts[9]	Liquid	0.050	4950	31000	78000	22000

[1] Planting on-farm treated seed was covered in the on-farm exposure studies. Planting commercial bulk seed is considered to be covered by on-farm treating and planting of seed as there is no additional exposure from loading seed from bags.

[2] Crops were designated into categories for assessment purposes as specific planting information were not available for all crops. Crop seed categories are based on similar use patterns such as comparable rates of application and amount of seed handled or planted per day. The highest values among the group were selected for use in the assessment.

[3] Liquid formulation includes solutions and suspensions.

[4] Maximum values were used in the assessment.

[5] Where MOE = margin of exposure; MOE = NOAEL/Exposure, based on the short- to intermediate-term dermal NOAEL of 20 mg/kg bw/day from oral reproductive toxicity study and dermal absorption of 14%. Exposure (mg/kg bw/day) = (Unit exposure (µg/kg a.i.) × Application Rate (kg a.i./kg seed) × Planting rate (kg seed/day) × DA (14%) × 0.001 mg/µg)/BW (80 kg)

[6] Where MOE = margin of exposure; MOE = NOAEL/Exposure, based on the short- to intermediate-term inhalation NOAEL of 20 mg/kg bw/ day from oral reproductive toxicity study and no respirator. Exposure (mg/kg bw/day) = (Unit exposure (µg/kg a.i.) × Application Rate (kg a.i./kg seed) × Planting rate (kg seed/day) × 0.001 mg/µg)/BW (80 kg)

[7] Calculated using the following equation: Combined MOE = 1/(1/dermal MOE + 1/inhalation MOE)

[8] There were insufficient data to assess grasses, non-grass animal feeds, and herbs and spices separately. The highest planting rates among the groups were selected for use in the assessment.

[9] The Zietz (2007) study was used. Although this study was conducted using a closed cab planter, this mitigation has been waived since the calculated MOEs were equal to or greater than 56 times the target MOE of 100 and this is sufficient to address the protection that would be provided by using a closed cab.

[10] Based on data submitted by the registrant for cumin (Hoekstra, 2011).

Appendix IV Proposed Label Amendments for Products Containing Fludioxonil

The label amendments below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements below.

A) For Technical Grade Products:

The following statement is proposed to be added under a new section titled **ENVIRONMENTAL PRECAUTIONS**:

> "TOXIC to aquatic organisms."

The following statement is proposed to be added under **PRECAUTIONS**:

> "DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters."

B) For Commercial Class Products:

The following statement is proposed to be added to all labels under **STORAGE**:

> "To prevent contamination, store this product away from food or feed."

Seed Treatment Products:

The following statement is proposed to be added to the primary and secondary panels of all seed treatment labels (except potato seed piece treatment labels):

> "For use with commercial seed treaters (facilities and mobile treaters)."

The following statement is proposed to be added to the primary and secondary panels of labels for potato seed piece treatment with dust formulations:

> "For on-farm use only."

The following statement is proposed to be added to all labels (under **PRECAUTIONS**) and tags of all bags containing treated seed for sale or use in Canada:

> "Keep out of reach of children and animals."

The following statements are proposed to be added under **ENVIRONMENTAL PRECAUTIONS**:

"TOXIC to aquatic organisms."

"Treated seed is toxic to small birds. Any spilled or exposed seeds must be incorporated into the soil or otherwise cleaned-up from the soil or other surfaces."

The following statements are proposed to be added under **USE RESTRICTION**:

"All bags containing treated seed for sale or use in Canada must be labeled or tagged as follows: "Toxic to small birds. Any spilled or exposed seeds must be incorporated into the soil or otherwise cleaned-up from the soil surface."

"Do not use fludioxonil to prime, film-coat, encrust, and/or pellet small seeds. For import use only."

Products Registered for Field and Turf Uses:

For turf products registered at a high application rate (e.g. Medallion Fungicide, Reg. No. 31528), the following statement is proposed to be added under **ENVIRONMENTAL PRECAUTIONS**:

"TOXIC to aquatic organisms and non-target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE."

For other products, use the following statement:

"TOXIC to aquatic organisms. Observe buffer zones specified under DIRECTIONS FOR USE."

The following statements are proposed to be added under **DIRECTIONS FOR USE**:

"Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) fine classification. Boom height must be 60 cm or less above the crop or ground."

"Airblast application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side."

"**DO NOT** apply by air."

Products Registered for Aerial Application:

The following statement is proposed to be added under **DIRECTIONS FOR USE**:

> "Aerial application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 16 km/h at flying height at the site of application. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) medium classification. To reduce drift caused by turbulent wingtip vortices, the nozzle distributions along the spray boom length MUST NOT exceed 65% of the wing- or rotorspan."

Buffer Zones

For turf products registered at a high application rate (e.g. Medallion Fungicide, Reg. No. 31528), the following buffer zones and corresponding statements are proposed to be added under **DIRECTIONS FOR USE**:

> "The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats."

Method of application	Crop		Buffer Zones (metres) Required for the Protection of:				
			Freshwater Habitat of Depths:		Estuarine/ Marine Habitats of Depths:		Terrestrial habitat
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer	Turf		3	1	1	0	1
	Outdoor ornamentals		1	1	0	0	0
Airblast	Outdoor ornamentals	Early growth Stage	20	1	0	0	0
		Late growth stage	10	1	0	0	0

> "For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners."

"The spray drift buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Pest Management Regulatory Agency web site."

For other products, use the following buffer zones and corresponding statements (under **DIRECTIONS FOR USE**) as appropriate:

"Use of the following spray methods or equipment **DOES NOT** require a buffer zone: hand-held or backpack sprayer and spot treatment."

"The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands)."

Method of application	**Crop**		**Buffer Zones (metres) Required for the Protection of Freshwater Habitat of Depths:**	
			Less than 1 m	**Greater than 1 m**
Field sprayer	Canola		2	0
	Ornamentals		3	0
	Crop Group 1B, spinach		4	1
	Pepper, tomato, bean, mustard green, turnip green, cabbage, carrot, onion, strawberry, blueberry (low bush), ginseng		5	1
	Turf		1	1
Airblast	Grapes	Early growth stage	15	1
		Late growth stage	10	1
	Blueberry (highbush), raspberry, blackberry, Saskatoon berry	Early growth stage	20	2
		Late growth stage	10	1
Aerial	Canola	Fixed wing	10	0
		Rotary wing	5	0

"For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners."

"The spray drift buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Pest Management Regulatory Agency web site."

Products Registered for Greenhouse and Postharvest Uses:

The following statement is proposed to be added under **ENVIRONMENTAL PRECAUTIONS**:

"TOXIC to aquatic organisms."

References

A. Information Considered in the Chemistry Assessment

List of Studies/Information Submitted by the Registrant

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B. Information Considered in the Toxicological Assessment

List of Studies/Information Submitted by the Registrant

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